EXHIBIT 3

Office Action Summary	Application No.	Applicant(s)	
	11/316,078	OLSON ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December, 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/20/2006; 07/31/2006; 08/02/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants: Graham P. Allaway et al.
Serial No.: 09/888,938
Filed: June 25, 2001
Exhibit 3

Detailed Office Action

Status of the Claims

Acknowledgement is hereby made of receipt and entry of preliminary amendments filed 21 December, 2005, and 20 March, 2006. Claims 1-32 have been canceled and new claims 33-41 submitted.

Information Disclosure Statement

The information disclosure statements filed 20 March, 2006, 31 July, 2006, and 02 August, 2007, have been placed in the application file and the information referred to therein has been considered.

Applicants are reminded that the listing of references in the specification (e.g., see pages 72-84, 98-108, and 110) is not a proper information disclosure statement. 37 C.F.R. § 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and M.P.E.P. § 609A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited or considered by the examiner on a form PTO-892 or PTO-1449, they have not been considered.

37 C.F.R. § 1.84

Acknowledgement is hereby made of receipt and entry of the drawings filed on 21 December, 2005, which are deemed to be acceptable.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37-41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims employ the term "about" in reference to the dosage which renders the claims indefinite since the precise concentrations to be administered cannot be readily ascertained. For instance, what constitutes "about" 2 mg? Does the term encompass 1 mg, 1.5 mg, 1.75 mg, 2.25 mg, 2.5 mg, or 3 mg? How can the skilled artisan actually ascertain the metes and bounds of the patent protection desired? Appropriate correction is required.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to

> a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Wu and Mackay (1998). Wu and associate describe the isolation and preliminary characterization of two novel anti-CCR5 IgG Mabs designated 5C7 and 2D7. Methods of making chimeras/humanized antibodies were also provided. Methods of inhibiting HIV infection in a patient were also contemplated. This teaching does not disclose the precise parameters pertaining to dosage and degree of reduction in viral load. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to administer Mabs 5C7 and 2D7 to HIV-infected patients to inhibit viral replication. The inhibition of viral replication would be associated with a reduction in viral load. The optimal effective dosage could easily be determined through routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 U.S.P.Q. 233, 235 (C.C.P.A 1955). *In re Peterson*, 315 F.3d 1330, 65 U.S.P.Q.2d 1382. *In re Hoeschele*, 406 F.2d 1403, 160 U.S.P.Q. 809 (C.C.P.A. 1969). *In re Kulling*, 897 F.2d 1147, 14 U.S.P.Q.2d 1056 (Fed. Cir. 1990). *In re Geisler*, 116 F.3d 1465, 43 U.S.P.Q.2d 1362 (Fed. Cir. 1997).

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode

contemplated by the inventor of carrying out his invention.

Scope of Enablement

Claims 33-41 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The claims are broadly directed toward methods of reducing the HIV-1 viral load in a subject by administering an IgG anti-CCR5 monoclonal antibody. The specification discloses the identification and preliminary characterization of a small panel of six Mabs designated PA8, PA9, PA10, PA11, PA12, and PA14. PA14/PRO140 appears to display the greatest antiviral activity. Appropriately drafted claim language directed toward this embodiment would obviate the rejection.

The legal considerations that govern enablement determinations pertaining to undue experimentation have been clearly set forth. *Enzo Biochem, Inc.*, 52 U.S.P.Q.2d 1129 (C.A.F.C. 1999). *In re Wands*, 8 U.S.P.Q.2d 1400 (C.A.F.C. 1988). *Ex parte Forman* 230 U.S.P.Q. 546 (PTO Bd. Pat. App. Int., 1986). The courts concluded that several factual inquiries should be considered when making such assessments including the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims. *In re Rainer*, 52 C.C.P.A. 1593, 347 F.2d 574, 146 U.S.P.Q. 218 (1965). The disclosure fails to provide adequate guidance pertaining to a number of these considerations as follows:

1) The claims encompass a potentially large genus of structurally/functionally distinct immunoglobulins. The claims simply specify that an anti-CCR5 IgG Mab is to be administered. However, there are no limitations pertaining to the structural and well-characterized functional characteristics of the claimed antibodies.

2) The disclosure fails to provide adequate guidance pertaining to the molecular determinants modulating antigen-antibody binding interactions. There is no discussion about those CCR5 epitopes that lead to the development of a strong immune response. Thus, the skilled artisan cannot determine if any given antibody will prove to be a useful therapeutic.

3) The disclosure fails to provide adequate guidance pertaining to functional properties of any given antibody. There is no discussion concerning the binding affinity, avidity, specificity, etc. Simply identifying antibodies that bind to CCR5 does not guarantee that said antibodies will have the requisite immunological properties that make them useful therapeutically.

4) The disclosure fails to provide a sufficient number of working embodiments. Considering the claim breadth, it would require more than a single Mab to enable the full breadth of the claimed invention.

5) The development of HIV immunotherapeutics has been problematic and ineffective (Montefiori, 2005; Haynes *et al.*, 2005; Trkola *et al.*, 2005). This is due to poor titers and binding affinities of the Mabs of interest.

When all the aforementioned factors are considered *in toto*, it would clearly require undue experimentation to practice the invention.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 U.S.P.Q.2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); and *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) or § 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Provisional Rejections

Claims 33-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being

unpatentable over claims 33-55 of copending Application No. 11/451,707. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '707 application disclose the administration of a CCR5-specific IgG Mab (PA14) that is capable of reducing the viral load in a subject thereby anticipating the claimed invention. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 33-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29, 30-37, 42, 47, and 90 of copending Application No. 11/491,330. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '330 application disclose the administration of a CCR5-specific IgG Mab (PA14) that is capable of reducing the viral load in a subject thereby anticipating the claimed invention. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 33-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 98-112 of copending Application No. 11/804,746. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '746 application are directed toward methods of treating HIV-1 infection in a subject by administering Mab PA14. Clearly the administration of PA14 to an infected subject would result in a reduction in viral load. Accordingly, the claims are not patentably distinct. This is a provisional obviousness-type

double patenting rejection because the conflicting claims have not in fact been patented.

Claims 33-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 61 of copending Application No. 11/894,568. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '568 application are directed toward the administration of an anti-CCR5 Mab with similar characteristics and is not patentably distinct. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Non-provisional rejections

Claims 33-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-32 of U.S. Patent No. 7,122,185. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '185 patent are directed toward treatment methods by administering humanized PRO140/PA14 which anticipates, or renders *prima facie* obvious, the claimed invention.

Claims 33-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 7,060,273. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the '273 patent are directed toward methods for the reduction of HIV-1 viral loads by administering an antibody comprising portions of PA14. Thus, the claimed inventions are not patentably distinct.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin, Ph.D./
Primary Examiner, Art Unit 1648

27 March, 2008

Notice of References Cited	Application/Control No. 11/316,078	Applicant(s)/Patent Under Reexamination OLSON ET AL.	
	Examiner Jeffrey S. Parkin, Ph.D.	Art Unit 1648	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
*	N	WO 98/18826	05-1998	WO	Wu, L.	
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Montefiori, D. C.,2005, Neutralizing antibodies take a swipe at HIV in vivo, Nat. Med. 11(6):593-594.
	V	Trkola, A., et al., 2005, Delay of HIV-1 rebound after cessation of antiretroviral therapy through passive transfer of human neutralizing antibodies, Nat. Med. 11(6):615-622.
	W	Haynes, B. F., et al., 2005, Cardiolipin polyspecific autoreactivity in two broadly neutralizing HIV-1 antibodies, Science 308:1906-1908.
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/316,078	12/21/2005	William C. Olson	64672-AA/JPW/AJD	9002

23432 7590 04/09/2008

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
04/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

EXHIBIT 4

Office Action Summary	Application No.	Applicant(s)	
	11/400,497	ALLAWAY ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49,53 and 55-58* is/are pending in the application.

4a) Of the above claim(s) *56-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49,53 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants: Graham P. Allaway et al.
Serial No.: 09/888,938
Filed: June 25, 2001
Exhibit 4

DETAILED ACTION

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 17, 2008 has been entered. The RCE follows;

Response to Amendment

The amendment and response filed on March 17, 2008 have been acknowledged. Claims 49 and 53 have been amended. In summery, claims 1-48, 50-52, 54 have been canceled. Clams 49, 53, 55-58 are pending. Claims 56-58 are withdrawn from consideration. Claims 49, 53, 55 are considered before the examiner.

Priority

1. The priority of claims 49, 53 and 55 based on the provisional Application SN. 60,019,941 filing date on June 14, 1996 has been accepted in view of Applicants' amendment.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

3. Claims 49 and 53 are still rejected under 35 U.S.C. 102(b) as being anticipated by Samson et al. (Biochemistry, March 1996, Vol. 35, pp. 3362-3367).

4. Applicants traverse the rejection and submit that the claims 49 and 53 are now amended to be only portion of CCR5 and not the polypeptide with 352 consecutive amino acid s set forth in SEQ ID NO: 7 as disclosed by Samson et al. Therefore, the rejection should be withdrawn.

5. Applicants' argument and amendment have been respectfully considered; however, they are not found to be persuasive to overcome rejection. The arguments do not comply with 37 CFR 1.111(c). The amendment still fails clearly point out the patentable novelty which he or she thinks the claims present in view of the references cited in the office action. Further, Applicants do not show how the amendments avoid such references or objections. The open language "include' cited in claim 49 still fails to limit and define the claimed polypeptide being less than 352 amino acids of the CCR5. Instead, a reasonable interpretation of the claimed polypeptide cited in claim 49 is any polypeptide containing a portion of human CCR5 that include the sequence set forth in SEQ ID NO: 7. The polypeptide cited in claim 53 is the polypeptide with the sequence set forth in SEQ ID NO: 7.

6. Because Samson et al. teach the CCR5 with the identical sequence set forth in SEQ ID NO: 7, claims 49 and 53 are still anticipated by Samson et al. The rejection is maintained.

7. Claims 49, 53 and 55 are still rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,025,154 A, 6,800,729B2, 6.511, 826B2 all to Li et al. , or 6,265,184B1 to Gray et al.

8. In the response, Applicants submit that since claim 49 has been amended, the claimed polypeptide is not a polypeptide with 352 consecutive amino acids as disclosed in the cited patents. It is only a portion of the 352 amino acids of Human CCR5, which includes the sequence set forth in SEQ ID NO: 7 and it inhibit fusion of HIV-1 to a CD4+ cell. None of the cited patents disclose any specific portion of the 352 amino acid polypeptide set forth in SEQ ID NO: 7 and it inhibits the fusion of HIV-1 to a CD4+ cell.

9. Applicants' argument and amendment have been respectfully considered; however, however, they are not found to be persuasive to overcome rejection. Applicant's arguments do not comply with 37 CFR 1.111(c) and are not persuasive to withdraw the rejection. Because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. In the instant case, the amendment "include" is still considered as an open language that fails to limit the claimed polypeptide being less than 352 amino acids long or being any particular fragment of the CCR5. Therefore, claim 49 still read on an isolated polypeptide comprising an amino acid residues set forth in SEQ ID NO: 7. Claim 53 is still read on a polypeptide with amino acid sequence set forth in SEQ ID NO: 7. the cited references therefore, still anticipate the claims. The rejections are maintained.

10. Regarding the biological function of inhibitory effect against HIV-1 infection, applicants' attention is directed to Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21), in that article, Feit et al. teach three criteria for analysis whether the prior art is inherently anticipate a claim(s). (1). The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility.** (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can,* state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing.

11. In the instant case, the CCR5 polypeptide disclosed by all cited patents comprises the identical sequence to the claimed polypeptide set forth in SEQ ID NO: 7. Therefore, it certainly and inherently exhibits the same biological function of the human CCR5 even though the cited references may be silent about the biological function and/or the biological function may be found later. Feit et al. further point out that: if a person having ordinary skill presented with the fact would understand that the prior art inherently

disclose a claimed element, the element is anticipated. It is irrelevant whether the understanding was apparent at the time of filing the application in question, or first becomes apparent at a later time.

12. The rejection of Claims 49 and 53 under 35 U.S.C. 102(b) as being anticipated by Raport et al. submitted to NCBI AAC50598 on April 12, 1996 has been removed necessitated by Applicants' amendment.

13. The rejection of Claims 49, 53 and 55 under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,448,375B1 has been removed necessitated by Applicants' amendment.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Bao Qun Li/

Primary Examiner, Art Unit 1648

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The time period for reply, if any, is set in the attached communication.